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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,079	10/13/2000	Robert E. Herman	F-5076-DIV	8404

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EXAMINER
PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
1639	11

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/688,079	Herman et al
Examiner	**Art Unit**
Padmashri Ponnaluri	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 6, 2003*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *38-43, 62, and 70* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *38-43, 62, and 70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☒ The proposed drawing correction filed on *Oct 13, 2000* is: a) ☐ approved b) ☒ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment B and the response filed on 2/6/03 have been considered and entered into the application.

2. Claims 44-61 and 71-76 have been canceled by the amendment B, filed on 2/6/03.

3. Claims 38-43, 62 and 70 are currently being examined in this application.

4. The preliminary amendment A, filed on 10/13/00 has been fully considered, and entered in part. The amendment to the drawings and to the specification pages 15, 16 and 18, has been considered and not have been entered, since it introduces new matter.

5. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10/13/00 have been disapproved because they introduce new matter into the drawings. 37 CAR 1.121(a)(6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of changes to the drawings.

6. The formal drawings filed on 2/6/03 are not considered, since applicants response filed on 2/6/03 failed to address the new matter issue of the amended drawings filed on 10/13/00.

7. In view of the amendment and arguments the rejection of claim 70 under 35 U. S. C. second paragraph set forth in the previous office action has been withdrawn.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The rejection of claims 38-43, 62, 70 under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,319,662 B1 (Foley et al) is maintained for the reasons of record.

10. The rejection of claims 38-43, 62, under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,300,019 (Bischof et al) and US Patent 6,319,662 B1 (Foley et al) is maintained for the reasons of record.

11. Claims 38-43, 62, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,319,662 B1 (Foley et al).

The instant claims briefly recite a kit comprising a tubing , a transfer container, photo active material, and an overlap enveloping at least a portion of the kit.

Foley et al teach a method and apparatus for treating a body fluid to at least substantially inactivate viral contaminants that may be present therein. The reference in figure 1, discloses a container 10 (refers to the transfer container of the instant claims) including the blood component, and the blood component is added to the viral inactivating agent 13 (refers to photo activating material of the instant claims). The reference teaches that the viral inactivating agent can be methylene blue (i.e., see column 4) (refers to instant claim 39) or psoralen (i.e., see column 2, line 67) (refers to instant claim 42). The reference teaches that the container 10 will include a fluid line 12 (refers to the tubing of the instant claims) that will be coupled to a column (i.e, see column 4, lines 42-43). The reference teaches that the after the container containing the blood product and viral inactivating agent is activated by light of an appropriate wavelength, the resultant product flows through fluid line 12 into the affinity column 14. The affinity column 14 will remove excess viral inactivating agents as well as photo products (i.e., see column 4, lines 58-63). The reference teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines (refers to the instant claim 41). The reference in example 3 teaches the method of treating blood component with methylene blue and photo activating the blood component and filtering the product to remove the remaining photo activating agents.

The claimed invention differs from the prior art teachings by reciting a kit; and a kit comprising a first filtration media and second filtration media; and fist and second blood cellular species.

However, based on the reference disclosure of apparatus, it would be obvious to one skilled in the art at the time of the invention to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime. The reference does not recite two different filtration media to eliminate two different species of blood components. However, the reference teaches that the irradiated blood components are passed through different types of filters to remove the excess viral inactivating agent and photo products. Thus it would have been obvious to one skilled in the art at the time the invention was made to use different filters to remove different components, such that selected blood components are obtained.

12. Claims 38-43, 62, are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,300,019 (Bischof et al) and US Patent 6,319,662 B1 (Foley et al).

Foley et al has been discussed supra.

Bischof et al teach a system and methods for eradicating contaminants using photo active materials in fluids like blood. The reference teaches that the device includes an outer wall that defines the interior area. The outer wall is transparent to radiation within a prescribed wavelength to thereby pass the radiation into the interior area. The treatment chamber is formed in the interior area for receiving the fluid be treated , and the fluid carries one or more contaminants to which a photo activating agent is bound. The reference teaches that a single source of radiation is positioned outside the housing. The system envelopes both the housing and source with a reflective surface that focuses radiation from the source or sources into the housing (see column 2). The reference figure 1 shows a system 10 for treating fluid carrying a contaminant. The system includes a treatment device 12 that receives fluid from a source container 14 and conveys after the fluid treatment to a collection chamber 16. The fluid in the source container 14 includes a photo active material that has an affinity for biological contaminant carried by the fluid. The treatment device 12 includes a housing 18 (refers to the overlap of the instant claims) that defines a treatment chamber 20.the housing wall 22 is made from a material that is essentially transparent to the radiation to thereby pass the radiation into the accurate gap 26. The radiation chamber 50 includes single source of radiation 52 and a reflector that envelops both the radiation source 52 and treatment device 12. The reference in figure 14 shows the treatment chamber, which includes a inlet 30 to the treatment device 12 includes the length of flexible inert plastic tubing 34. The tubing 34 includes a conventional filter 100 for removing the white blood cells from the fluid prior to entering the treatment device.

The reference does not recite different photo activating reagents such as psoralen, methylene blue and phthalocyanine. However, Foley et al teaches that the viral inactivating agents are chosen from the group; porphyrin, psoralens, phthalocyanines and methylene blue.

The claimed invention differs from the combined teachings of references Bischof et al and Foley et al by reciting a kit. However, based on the reference disclosure of apparatus, it would be obvious to one skilled in the art at the time of the invention to group all the components of the apparatus used in the method in a kit for ease of use, such that the components can be packed together enables one skilled in the art to assemble them together to use anytime.

13. Applicant's arguments filed on 2/6/03, regarding the art rejections of claims over Foley et al, and Foley and Bischof et al, have been fully considered but they are not persuasive. .

Applicants argue that neither Foley nor Bischof and Foley teach or suggest a kit that includes a source of photoactive material to be mixed with blood constituent, which is enveloped by an overwrap that absorbs light that activates photoactive material, thereby preventing degradation of the photoactive material prior to use (see specification , page 13, lines 8-20).

Applicants arguments have been considered but are not persuasive. Foley et al teach that the blood component is added to the viral inactivating agent 13 (refers to photo activating material of the instant claims) and for example figure 1 discloses the system which has a container (10), and the container walls would refer to the overwrap enveloping a portion of the kit, which includes the viral inactivating agent (or the photoactive material). The reference specifically do not teach that the overwrap includes light filtering material. However, the reference teaches that the container 10 containing the blood component and the viral inactivation agent is activated by light of an appropriate wavelength. Thus, the walls of the container of the reference system absorbs light that activates the photoactive material.

Applicants arguments regarding the 'thereby preventing degradation of the photoactive material prior to use (see specification , page 13, lines 8-20)' have been considered but are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., preventing degradation of the photoactive material prior to use) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejections of record have been maintained for the reasons of record.

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
16 April 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER